DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0562]

Revised Compliance Policy Guide Sec. 110.300—Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised compliance policy guide (CPG) Sec. 110.300 entitled "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (registration CPG). The revised CPG provides written guidance to FDA's staff on enforcement of section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the agency's implementing regulation, which requires, beginning on December 12, 2003, registration with FDA for all domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States.

DATES: This revised CPG is final upon the date of publication. However, you may submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies of the revised CPG to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or

include a fax number to which the revised CPG may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revised CPG.

Submit written comments on the revised CPG to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT:

Food for human consumption: Judith Gushee, Center for Food Safety and Applied Nutrition (HFS–605), Food and Drug Administration, 301–436–2417.

Food for animal consumption: Isabel Pocurull, Center for Veterinary Medicine (HFV–226), Food and Drug Administration, 301–827–0175.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of revised CPG Sec. 110.300 entitled "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (registration CPG). This revised CPG outlines for FDA staff the agency's policy on enforcement of section 305 of the Bioterrorism Act and its implementing regulation ((68 FR 58894, October 10, 2003); (codified at 21 CFR part 1, subpart H, 1.225 through 1.243)). The Bioterrorism Act and subpart H require that, beginning on December 12, 2003, all domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States must be registered with FDA.

I. Background

On December 19, 2003, FDA issued CPG Sec. 110.300 (the December CPG). The December CPG states that for domestic firms, FDA would initially plan to focus the agency's efforts on educating and otherwise informing the industry

on how to comply with the registration of food facilities interim final rule, and that thereafter FDA would enforce the registration provision as appropriate in each situation. We set out in the Regulatory Action Guidance section our enforcement approach.

For foreign facilities, the December CPG referred to the policies set out in CPG Sec. 110.310 entitled "Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (the prior notice CPG).

II. Revised CPG Sec. 110.300

FDA is making only one substantive change in the registration CPG. Specifically, the revised CPG provides that, on November 8, 2004, FDA is fully implementing the agency's enforcement policy for domestic food facilities, which was set out in the Regulatory Action Guidance section of the December CPG. For foreign facilities, the registration CPG continues to state that generally, the registration requirement for the facilities of foreign manufacturers and shippers will be enforced in accordance with the policies set out in the prior notice CPG. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability for the revision to the prior notice CPG, which is being issued under § 10.115(g)(2) (21 CFR 10.115(g)(2)) as level 1 guidance that is effective November 8, 2004.

FDA is also issuing the revised registration CPG as level 1 guidance consistent with FDA's good guidance practices regulation (§ 10.115). Revised CPG Sec. 110.300 is being implemented immediately without prior public comment, under § 10.115(g)(2), because FDA has determined that prior public participation is not feasible or appropriate. Revision of FDA's prior notice enforcement policy directly affects the agency's enforcement of the registration

requirement for foreign manufacturers and shippers. Given this relationship, it is appropriate that FDA coordinate announcement and implementation of the agency's revised enforcement policy for food facilities registration with the agency's comparable actions for the prior notice of imported food requirement.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the revised CPG. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

An electronic version of this guidance is available on the Internet at *http://www.fda.gov/ora* under "Compliance References."

Dated: 11/2/04
November 2, 2004.

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Steve Niedelman,
Acting Associate Commissioner for Regulatory Affairs.

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